
Except as provided elsewhere in this policy, no investigator may involve a human being in research covered by this policy without the legally effective informed consent of the subject or the subject’s legally authorized representative. An investigator may seek consent only when the prospective subject or his/her representative has sufficient opportunity to consider participation, and in a manner that minimizes the possibility of coercion or undue influence. Information given to the subject or his/her representative will be in language and rendered in a manner understandable to the subject or the representative. No informed consent, whether oral or written, may include exculpatory language that waives or appears to waive the subject’s legal rights or releases or appears to release the investigator, sponsor, institution or its agents from liability for negligence.

a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, the following information shall be provided to each subject during the consent process:

- A statement that the study involves research, an explanation of study purposes and expected duration of the subject’s participation, a description of procedures to be followed, and identification of any experimental procedures;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others that may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A description of the extent to which confidentiality of records identifying the subject will be maintained;
- For research involving more than minimal risk, an explanation of any compensation and an explanation of any available medical treatments if injury occurs and, if so, their nature and/or how to obtain further information;
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and in the event of a research-related injury; and
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the right to discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
b) Additional elements of informed consent. When appropriate, one or more of the following elements should be provided to each subject:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation;
- A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject; and
- The approximate number of subjects involved in the study.

c) The IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent described above, or waive the requirement to obtain informed consent if:

- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
  - Public benefit or service programs;
  - Procedures for obtaining benefits or services under those programs;
  - Possible changes in or alternatives to those programs or procedures; or

- Possible changes in methods or levels of payment for benefits or services under those programs; and
- The research could not practicably be carried out without the waiver or alteration.
d) An IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent if:
   ➢ The research involves only minimal risk to subjects;
   ➢ The waiver or alteration will not adversely affect subjects’ rights and welfare;
   ➢ The research could not practicably be carried out without the waiver or alteration; and
   ➢ Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

e) These informed consent requirements are not intended to preempt any applicable laws that require disclosure of additional information to ensure the legality of informed consent.